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### REMARKS

This is a full and timely response to the final Official Action mailed July 26, 2007.

Reconsideration of the application in light of the above amendments and the following remarks is respectfully requested.

#### Request for Continued Examination:

Applicant hereby requests Continued Examination for this application and entry and consideration of this amendment consequent thereto.

## Claim Status:

Claims 22-53 and 63-79 were withdrawn from consideration under the imposition of a previous Restriction Requirement and cancelled without prejudice or disclaimer.

Subsequently, claims 59 and 61 were also cancelled without prejudice or disclaimer

By the forgoing amendment, various claims have been amended. Additionally, claim 2 has been cancelled without prejudice or disclaimer. No claims have been added. Thus, claims 1, 3-21, 54-58, 60, 62 and 80-99 are currently pending for further action.

### Previous Office Action:

All grounds of rejection in the previous Office Action of February 8, 2007 have been withdrawn by the recent final Office Action in response to Applicant's amendment filed May 8, 2007. New grounds of rejection are made by the recent final Office Action. Applicant addresses each of these below.

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## 35 U.S.C. § 112, second paragraph:

In the recent final Office Action, claim 55 was rejected under 35 U.S.C. § 112, second paragraph, as allegedly containing a recitation lacking proper antecedent basis. While Applicant does not necessarily agree that claim 55 was previously indefinite, claim 55 has been amended herein to address the issues raised by the Examiner under 35 U.S.C. § 112, second paragraph. Following this amendment, all the remaining claims are believed to be in compliance with 35 U.S.C. § 112 and notice to that effect is respectfully requested.

### Prior Art:

Claims 1, 2, 5-14, 21, 54, 57, 58, 60, 80, 86, 88, 91, 94, 96 and 99 were rejected under 35 U.S.C. § 102(e) by U.S. Patent App. Pub. No. 2003/0059471 to Compton et al. ("Compton"). Applicant notes that, while independent claim 54 was not listed in the Office Action under this or any other ground of rejection, claim 54 was mentioned in the text of the rejection based on Compton. Therefore, claim 54 is addressed in this section.

This rejection is respectfully traversed for at least the following reasons.

# Claim 1 now recites:

A method for producing an oral medication comprising:
with an inkjet dispenser, dispensing a structural material, said structural
material including one of a polymer or a gelatin;
curing said structural material; and

with said inkjet dispenser, dispensing a jettable pharmaceutical solution onto said cured structural material.

Support for the amendment to claim 1 can be found in Applicant's originally filed specification at, for example, paragraph 0021. In contrast, Compton does not teach or suggest this method.

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Compton teaches "flakes containing drugs and methods for forming and using such flakes." (Compton, abstract). According to Compton, these flakes can be formed by a variety of techniques. In a passing reference, Compton mentions forming the flakes using an inkjet. According to Compton, A "Spray, Inkjet or Drip Method" includes a first step: "[i]nkjet, spray, or drip drug slurry onto belt dryer or barrel or flat surface drying device." (Compton, paragraphs 0330-1). Compton then continues. "Once produced the flakes may be coated with a variety of agents for taste masking, controlled drug release, enteric release or for other purposes known by those skilled in the art of drug dosage coatings." (Compton, paragraph 0036).

However, Compton does not teach or suggest both "dispensing a structural material" "with an inkjet dispenser" and "with said inkjet dispenser, dispensing a jettable pharmaceutical solution onto said cured structural material." (Claim 1) (emphasis added). Compton does not ever teach, suggest or even mention using an inkjet dispenser to dispense a jettable pharmaceutical solution onto a structural material.

"A claim is anticipated [under 35 U.S.C. § 102] only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). See M.P.E.P. § 2131. For at least these reasons, the rejection based on Compton of claim 1 and its dependent claims should be reconsidered and withdrawn.

## Independent claim 54 recites:

A method for forming a slow release dosage of oral medication comprising: disposing a first layer of polymer based structural material adjacent to an inkjet dispenser;

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jetting a jettable pharmaceutical solution onto said polymer based structural material with said inkjet dispenser, wherein said solution comprises a solvent for dissolving said solution into said structural material.

(Emphasis added).

In contrast, as demonstrated above, Compton does not teach or suggest a method that includes "jetting a jettable pharmaceutical solution onto [a] polymer based structural material with [an] inkjet dispenser." Compton does not ever teach, suggest or even mention using an inkjet dispenser to dispense a jettable pharmaceutical solution onto a structural material. For at least this reason, the rejection of claim 54 should be reconsidered and withdrawn.

Compton further does not teach or suggest that a jetted pharmaceutical "solution comprises a solvent for dissolving said solution into said structural material." In this regard, the final Office Action cites Compton at paragraphs 0021 and 0308. (Action of 7/26/07, p.

3). These paragraphs, in their entirety recite the following.

[0021] According to another aspect of the invention, a method is provided for preparing a pharmaceutical preparation. The method involves incorporating a drug into or upon a plurality of flakes. In one embodiment, the flakes are formed first, and then the drug is coated onto, or allowed to penetrate into, the flakes. In another embodiment, the drug is incorporated into the flakes by forming the flakes in the environment of the drug.

[0308] The active compounds of the present invention may be a pharmaceutical composition having a therapeutically effective amount optionally included in a pharmaceutically-acceptable carrier. The term "pharmaceutically-acceptable carrier" as used herein means one or more compatible solid or liquid-filler, dilutants or encapsulating substances which are suitable for administration to a human or other animal. The term "carrier" denotes an organic or inorganic ingredient, natural or synthetic, with which the active ingredient is combined to facilitate the application. The components of the pharmaceutical compositions are capable of being commingled with the flakes of the present invention, and with each other, in a manner such that there is no interaction which would substantially impair the desired pharmaceutical efficacy.

Neither of these portions of Compton teach or suggest a method that includes jetting a pharmaceutical solution using a solvent that then dissolves the solution into a structural material, as recited in claim 54.

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"A claim is anticipated [under 35 U.S.C. § 102] only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). See M.P.E.P. § 2131. For at least these reasons, the rejection based on Compton of claim 54 and its dependent claims should be reconsidered and withdrawn.

The various dependent claims of the application also recite subject matter that is further patentable over the cited prior art. Specific, non-exclusive examples follow.

Claim 21 recites "further comprising dispensing a plurality structural material layers over said jettable pharmaceutical solution to control a release rate of said pharmaceutical solution." In this regard, the Office Action cites Compton at paragraphs 0042-44. However, this portion of Compton merely teaches that some flakes are uncoated for quick drug release, while others have a coating for delayed release. "The thickness of such coatings, of course, also can be varied, whereby some flakes are exposed for drug delivery prior to others, thereby effecting an extended drug-release profile." (Compton, paragraph 0042). This does not teach or suggest dispensing a plurality of structural material layers over the jetted pharmaceutical solution to control the release rate. For at least this additional reason, the rejection of claim 21 should be reconsidered and withdrawn.

Claim 55 recites "depositing a second layer of polymer based structural material over said pharmaceutical solution; and varying a quantity of said first and second layer of polymer based structural material to vary a release rate of said pharmaceutical solution." Claim 55 was not listed in any of the prior art rejections. However, Applicant believes that claim 55 is patentable over the cited prior art for at least the same reasons as given above with respect to claim 21.

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Claim 85 recites "heating said inkjet dispenser." The final Office Action does not address claim 85. Claim 85 is not included in any of the rejections in the final Office Action. Consequently, there appears to have been no valid rejection of claim 85 made. Thus, claim 85 appears to be patentable over the cited prior art.

Claim 86 recites "wherein disposing said first layer of structural material comprises depositing said first layer of structural material onto a non-adhesive substrate." Claim 94 recites similar subject matter. In this regard, the Office Action cites Compton at paragraph 0330. However, this portion of Compton does not even mention a "non-adhesive substrate." The cited portion of Compton states: "Inkjet, spray, or drip drug slurry onto belt dryer or barrel or flat surface drying device." (Compton, paragraph 0330). There is no mention here of the claimed "non-adhesive substrate." For at least these reasons, the rejection of claims 86 and 94 should be reconsidered and withdrawn.

Claims 87 and 95 recite "wherein said non-adhesive substrate comprises glass or polytetrafluorethylene." The claims are not addressed in the final Office Action, no rejection of these claims has been made. Thus, claims 87 and 95 appear to be patentable over the cited prior art..

Claim 89 recites "wherein said edible substrate comprises a sheet of edible polymer."

Claim 97 recites similar subject matter. The final Office Action does not address claims 89 and 97. Claims 89 and 97 are not listed in any rejection. Consequently, there appears to have been no valid rejection of claim 89 and 97 made. Claims 89 and 97 appear to be patentable over the cited prior art.

Claims 15-20, 60, 62 and 83 were rejected under 35 U.S.C. § 103(a) over the combined teachings of Compton and U.S. Patent No. 6,602,511 to von Corswant

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("Corswant"). This rejection is respectfully traversed for at least the same reasons given above in favor of the independent claims.

Additionally, claim 20 recites: "wherein said jettable vehicle component further comprises one of a humectant, a surfactant, a colorant, a drier, a thinner, a wax, a lubricant, a reducing oil, a solvent, a body gum, a binding varnish, an antioxidant, an anti-skinning agent, a resin, or a binder." Claims 83 and 84 recite similar subject matter.

The Office Action does not appear to address these claims specifically and does not clearly indicate how or where the cited prior art teaches or suggests this subject matter. For at least these additional reasons, the rejection of claims 20, 83 and 84 should be reconsidered and withdrawn.

Claims 3, 4 and 56 were rejected under 35 U.S.C. § 103(a) over the combined teachings of Compton and U.S. Patent App. No. 2003/0065294 to Lo et al. ("Lo"). This rejection is respectfully traversed for at least the same reasons given above in favor of the independent claims.

Claims 81, 82, 92 and 93 were rejected under 35 U.S.C. § 103(a) over the combined teachings of Compton, Corswant and DD 217989 to Bombor et al. ("Bombor"). This rejection is respectfully traversed for at least the same reasons given above in favor of the independent claims.

Additionally, claim 82 recites "varying said solvent to control release characteristics of said pharmaceutical solution." Claim 93 recites similar subject matter. In contrast, cited prior art does not teach or suggest changing or "varying" the solvent used to "control release characteristics of said pharmaceutical solution." The final Office Action does not specifically

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address claims 82 and 93 or explain how or where this subject matter is taught by the prior art. For at least these additional reasons, the rejection of claims 82 and 93 should be reconsidered and withdrawn.

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#### Conclusion:

In view of the following arguments, all claims are believed to be in condition for allowance over the prior art of record. Therefore, this response is believed to be a complete response to the Office Action. However, Applicants reserve the right to set forth further arguments supporting the patentability of their claims, including the separate patentability of the dependent claims not explicitly addressed herein, in future papers. Further, for any instances in which the Examiner took Official Notice in the Office Action, Applicants expressly do not acquiesce to the taking of Official Notice, and respectfully request that the Examiner provide an affidavit to support the Official Notice taken in the next Office Action, as required by 37 CFR 1.104(d)(2) and MPEP § 2144.03.

If the Examiner has any comments or suggestions which could place this application in even better form, the Examiner is requested to telephone the undersigned attorney at the number listed below.

Respectfully submitted,

DATE: September 26, 2007

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## CERTIFICATE OF TRANSMISSION

I hereby certify that this correspondence is being transmitted to the Patent and Trademark. Office facsimile number <u>571-273-8300</u> on

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